DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

m2857n

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 6 1999

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Bernard R. Garbe, Managing Director
Vitalograph (Ireland) Ltd.
Gort Road, Ennis Industrial Estate
Ennis, County Clare
IRELAND

Dear Mr. Garbe:

We are writing to you because on May 31-June 3, 1999, an investigator from the Food and Drug Administration (FDA) collected information that revealed serious regulatory problems involving your spirometers and peak flow meters.

Under a United States Federal law, The Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The spirometers and peak flow meters manufactured by your firm are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Quality System Regulation (QS Regulation), Title 21, Code of Federal Regulations, Part 820. We received your response to the FDA 483 on July 6, 1999, and will include your responses and our list of violations as follows:

1. Failure to establish and maintain procedures to adequately control environmental conditions which could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(c). For example, employees checked out wrist straps without documenting the daily ESD test as required by their written procedure.

Your firm's response was that training employees would occur, however, your ESD reduction procedure is incomplete and must be updated to reflect the changes you are proposing. This response is inadequate.

2. Failure to establish procedures for identifying training needs for employees so that they may adequately perform their assigned duties, as required by 21 CFR 820.25(b). For example: a) your firm failed to adequately train employees not to bring items into the work area that may damage sensitive components; and b) lack of training for employees performing complaint handling.

Your firm's response was that training will commence on new employment which will include a sign off sheet, existing employees will be given a refresher course and records will show proof of training, and that posters highlighting materials that are unacceptable in an Electrostatic Discharge (ESD) sensitive environment will be posted in the plant. You have not provided documentation of the training procedure. In order for this to be a complete response, you must provide this documentation. This response is inadequate.

3. Failure to maintain procedures for storage to ensure that deterioration and contamination or other adverse effects to product does not occur, as required by 21 CFR 820.150. For example, the firm stores paperwork inside static shielding bags with PCBs and static shielding bags were found unsealed.

Your firm's response is the same as #2 above. This response is inadequate.

4. Failure to establish and maintain process control procedures for the monitoring and control of process parameters during production, as required by 21 CFR 820.70(a) and (b). For example, the firm failed to measure the temperature of the wave-soldering machine at the start of every PCB Kit as stated in the soldering machine SOP.

Your firm's response was that the procedure for the use and maintenance of the wave-solder machine would be rewritten to reflect the firm's requirements. You did not provide the rewritten document. This response is inadequate.

5. Failure to ensure all equipment used in the manufacturing process meets specified requirements, as required by 21 CFR 820.70(g). For example, the firm failed to set the machine control settings for the soldering machine at 6.5 as required by their written procedure. The speed was set at 6.

Your firm's response was that the procedure would be rewritten to reflect the firm's requirements. You did not provide the rewritten document. This response is inadequate.

6. Failure to maintain schedules for maintenance of equipment to ensure that manufacturing specifications are met, as required by 21 CFR 820.70(g)(1). For example, there is no schedule for changing the solder bath nor has the firm completed an assay to check the solder for contamination to know what an appropriate schedule should be. In addition, specific gravity of the flux sprayed on the PCBs has not been checked.

Your firm's response was that they would take advice from their solder supplier technical department on the frequency of assaying required and then introduce a schedule based on their recommendations. The firm will require certification of conformance from their supplier for the flux and specific gravity for all batches in the future. You did not provide documentation. This response is inadequate.

7. Failure to ensure adherence to applicable equipment maintenance schedules, as required by 21 CFR 820.70(g)(2). For example, monthly and quarterly wave-soldering machine maintenance was not documented for 1998 and 1999 nor could the firm locate maintenance records for 1995, 1996, or 1997.

Your firm's response was that you would rewrite the monthly and quarterly maintenance requirements for the wave-soldering machine. You did not provide documentation. This response is inadequate.

8. Failure to validate and document a manufacturing process, as required by 21 CFR 820.75(a). For example, although your firm stated that they validated the ATE PCB test equipment, there was no documentation to substantiate that it was performed.

Your firm's response is that every effort will be made to acquire validation documentation for existing PCBs and all future boards will have validation documentation. You did not provide documentation. This response is inadequate.

9. Failure to adequately validate software for its intended use according to established protocol and to document activities and results, as required by 21 CFR 820.70(i). For example, the software was not adequately validated for its intended use nor documented appropriately.

Your firm's response is that all validation procedures will be written for the software processes listed above. You did not provide documentation. This response is inadequate.

10. Failure to establish and maintain procedures for implementing corrective and preventive actions to identify existing and potential causes of nonconforming product and to use appropriate statistical methodology to detect recurring quality problems, as required by 21 CFR 820.100(a)(1). For example, when the firm decided to separate complaints from service reports, the service reports were no longer monitored by Vitalograph nor were they sent to the Ennis facility. Some of the reports reviewed by the investigator were determined to meet the definition of a complaint and they should have been followed-up as a complaint for corrective and preventive action. In addition, your firm did not complete their complaint trending by failure mode to determine recurring problems.

Your firm's response was that all complaints and service reports will be monitored in the future and trending of complaint reports will be introduced. You did not provide documentation. This response is inadequate.

11. Failure to investigate the cause of nonconforming product, as required by 21 CFR 820.100(a)(2). For example, there were several complaints concerning defective or missing pointers on peak flow meters, including complaint #23166 dated 8/29/97,which did not have corrective action documented. The manager stated that it could have been operator error so they instituted retraining. However, the investigator found another complaint in Dec. 1998 when again there was no corrective action documented. There was no training documented to include results of possible inaccurate pointer assembly.

This violation was not noted on the FDA 483.

12. Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198(a). For example, the complaint handling procedure does not include a definition of what the firm considers a complaint so that there is a basis for employees to make a consistent determination of a complaint or a service need.

Your firm's response was that training to ensure proper categorization of a complaint or service report will be conducted "where necessary" and the definition of a complaint will be added to the procedure. Training "where necessary" is too open to debate. You have not provided documentation. This response is inadequate.

In addition, your product is also misbranded within the meaning of Section 502 of the Act in that your firm failed to submit information to the Food and Drug Administration as required by the Medical Device Reporting (MDR) Regulation, as specified in Title 21 Code of Federal Regulations, Part 803 as follows:

13. Failure to develop, maintain, and implement a written MDR procedure, as required by 21 CFR 803.17. For example, the Ennis facility lacks a written MDR procedure as required by the July 1996 regulation.

This violation was not noted on the FDA 483.

14. Failure to establish and maintain MDR event files, as required by 21 CFR 803.18. For example, all adverse events are contained in the same filing system rather than designating a separate file system for MDRs.

This violation was not noted on the FDA 483.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

Given the serious nature of these violations of the Act, the spirometers and peak flow meters manufactured by Vitalograph (Ireland) Ltd. may be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, the implementation of your corrections has been verified, and you are notified that your corrections are adequate, your company may resume entry of these devices into this country.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all products manufactured, distributed, held, and labeled by your firm are in compliance with the provisions of the Act.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter the steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please address your response to:

Edgardo Santiago
Food and Drug Administration
Center for devices and Radiological Health
Division of Enforcement III
Orthopedic, Physical Medicine & Anesthesiology Devices Branch
2098 Gaither Road
Rockville, MD 20850

If you have any questions, please contact Brenda Hayden at (301) 594-4659.

Sincerely yours,

Gladys Rodriguez for.

Lillian J. Gill
Director
Office of Compliance
Center for Devices and Radiological Health